COUNTY OF LOS ANGELES - DEPARTMENT OF MENTAL HEALTH

OFFICE OF THE MEDICAL DIRECTOR

3.10 PARAMETERS FOR THE USE OF MEDICATION ASSISTED TREATMENT IN INDIVIDUALS WITH CO-OCCURRING SUBSTANCE USE DISORDERS

April 2015

I. Introduction:

A. The proper use of select medications can help treat specific substance use disorders, and is referred to as medication-assisted treatment (MAT).

B. MAT does not substitute for other appropriate psychosocial treatment interventions, and should be used in association with such interventions.

C. Prescribers who treat individuals with co-occurring substance use disorders should be familiar with, and include, the use of selected medications recognized as potentially useful for treatment of substance use disorders; e.g., acamprosate and naltrexone. Familiarity should include knowledge of proper use of each medication, including proper elements of assessment and management.

D. These parameters do not address the use of medications to ameliorate symptoms of substance intoxication or withdrawal, nor do they address opioid replacement therapy using methadone.

E. Use of MAT in individuals below 18 years of age should be associated with documentation in the medical record of the risk/benefit ratio.

II. Purpose:

To describe those situations in which MAT should be used to treat co-occurring substance use disorders in LAC DMH programs.

III. Alcohol Use Disorder:

A. Individuals being treated for mental illness, who have comorbid alcohol use disorder that has not responded to DMH psychosocial interventions during one year's time, and do not have contraindications for MAT, should be offered treatment trials of acamprosate, oral naltrexone, naltrexone Long-Acting Injectable (LAI,) gabapentin, disulfiram, and topiramate, The order of the trails should be based upon clinical presentation.

B. The medications, excepting those that are contraindicated or refused, should be offered sequentially until one of them is effective or the entire series has been tried.

1. The order of the sequential trials should be based upon clinical assessment and response monitoring.

2. Additional MAT may be attempted, using other medications or combinations in situations in which the evidence and risk/benefit ratio justifies the intervention, and is clearly documented.

C. For individuals that have been unsuccessfully treated for more than one year by DMH for comorbid alcohol use disorder, without use of MAT, documentation must be provided to explain why MAT has not been initiated.

IV. Opioid Use Disorder:

A. Individuals being treated for mental illness, who have comorbid opioid use disorder and do not have contraindications for MAT, should be offered naltrexone LAI.

B. For individuals who have been unsuccessfully treated for more than one year for comorbid opioid use disorder, without the use of MAT, the associated medical record must include documentation that justifies why MAT has not been initiated.

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V. Medication-Specific Parameters:

A. Acamprosate

In the absence of contraindications, acamprosate should be preferentially selected in lieu of other MAT for maintenance of abstinence in individuals with alcohol use disorder who are relatively stable and in early stages of recovery.

B. Buprenorphrine/naloxone

Buprenorphine/naloxone should be prescribed for treatment of opioid use disorder only in DMH programs that have been specifically approved for this activity by the Pharmacy Office.

C. Gabapentin

Gabapentin should be reserved for treatment of alcohol use disorder in instances in which acamprosate and naltrexone are ineffective, contraindicated, or there is a co-occurring mental disorder that requires gabapentin for treatment.

D. Naltrexone

1. In the absence of contraindications, naltrexone should be preferentially selected over other MAT for situations involving efforts to reduce ongoing alcohol consumption or significant craving.

2. Naltrexone LAI, if effective, should be continued for no more than 6 months without consultation and approval by the responsible clinical supervisor. Attachment 1: GUIDELINES FOR THE USE OF LONG ACTING INJECTABLE NALTREXONE (LAIN)

E Topiramate

Topiramate should be reserved for treatment of alcohol use disorder only when acamprosate and naltrexone are ineffective or contraindicated, or in the presence of a co-morbid disorder that requires topiramate for treatment.

VI. Attachments

1. GUIDELINES FOR THE USE OF LONG ACTING INJECTABLE NALTREXONE (LAIN)

2. URGE TO USE SCALE REFERENCED IN ATTACHMENT 1.

LOS ANGELES COUNTY DEPARTMENT OF MENTAL HEALTH

GUIDELINES FOR THE USE OF LONG ACTING INJECTABLE NALTREXONE (LAIN)
April 2015

I. Program Implementation: Consultation regarding administrative and clinical requirements for the use of LAIN in DMH programs is available through the DMH Pharmacy Bureau at (213) 738-4725.

II. DMH Program requirements for LAIN use

A. **Directly-operated programs:**

1. Appropriate knowledge by each program staff participating in LAIN-associated services.

   a. DMH Parameters for Medication Assisted Treatment.
   b. FDA prescribing and monitoring requirements for Naltrexone long-acting injectable preparation (LAIN), available as Vivitrol (Alkermes).

2. Availability and access to substance abuse treatment, including evidence based treatment services within the program.

3. Standardized procedure for acquisition of LAIN dose from pharmacy.

4. Proper storage facilities procedures for LAIN.

5. Availability of on-site supplies and facilities for on-site urine test for opioids.

B. **Contract agency programs:** Programs operated by agencies under contract to LACDMH should also meet the requirements outlined in this document before prescribing LAIN. Monitoring of adherence to these requirements and liability is the responsibility of the contract agency. On request, LACDMH staff is available for consultation to contract agencies to assist in meeting the requirements.

III. Client Selection for LAIN

A. Should be between ages 18 and 65, unless specifically approved by supervising psychiatrist.

B. If female, should be cautioned about unknown effect of Naltrexone in pregnancy, and have signed an informed consent form (DMH Outpatient Medication Review-MH 566).

C. Should currently meet DHCS medical necessity criteria for co-morbid specialty mental health services and DSM criteria for Alcohol or Opioid Use Disorders.

D. If Opioid Use Disorder is present, the client should have recently received detoxification from opioids and should be opioid-free for a minimum of 7 days.

E. If Alcohol Use Disorder, should express significant concern about persisting urges to drink.

F. Any client with the following conditions should not be started on LAIN therapy:

1. Acute hepatitis or liver failure
2. Opioid analgesics
3. Current opioid dependence
4. In acute opioid withdrawal
5. Positive urine screen for opioids
6. Unreliable history of being opioid free for at least 7 days
7. Fails a naloxone challenge test
8. Known previous allergic response to Naltrexone or LAIN

G. Special Populations

1. Pregnancy: LAIN is a *Pregnancy Category C* drug. There are no adequate or well controlled studies of either Naltrexone or LAIN in pregnant women. *Clients should sign a consent* documenting that they have been informed of LAIN's pregnancy category status.

2. Labor and Delivery: The potential effects on labor and delivery are unknown, and clients should be advised to inform their obstetrical provider if they are taking LAIN.

3. Nursing Mothers: Naltrexone should not be prescribed to nursing mothers without specific approval from the responsible supervising psychiatrist.

4. Pediatric Use: Naltrexone should not be used, as the efficacy and safety has not been established for any individuals under the age of 18.

5. Geriatric Use: Naltrexone should not be used, as the efficacy and safety has not been established for the geriatric population (>65 years old).

IV. Screening Requirements

A. **DMH-approved screening tools for Substance Use Disorder (SUD) severity**: Should be used at both baseline assessment and monthly for each client receiving LAIN.

1. For Alcohol Use Disorder, numerical result from the Urge to Drink Scale of 10 or more should be documented in the clinical record.
http://www.ndcrc.org/sites/default/files/urge_to_drink_scale_0.pdf

2. For Opioid Use Disorder, numerical result from the Urge to Use Scale of 10 or more should be documented in the clinical record. (Attachment 2)

B. **Medical History:** Should include current and past drug and alcohol use, allergies, psychiatric, legal, medical, surgical, family, and previous drug treatment history, recorded properly in the DMH clinical record.

C. **Physical Assessment:** A targeted physical assessment should include specific assessment for signs of addiction. Clients with identified primary medical conditions should be referred to primary care or other medical specialists.

D. **Laboratory Screening**

1. All clients should receive laboratory examination that includes standard metabolic screening, liver function panel, and Hep A, B, & C.

2. All clients should be screened for opioid use via urine dipstick immediately before each injection.

V. Informed consent

A. Signed Informed Consent to Treatment of LAIN must be obtained by a prescriber explaining the risks and benefits of LAIN.

B. Clients should be advised to wear a medical bracelet, if available, to help ensure proper pain management in case of an emergency.

VI. Dosage, Administration, and Storage

A. The standard FDA-approved dose is 380 mg delivered intramuscularly every 28-31 days.

B. The injection should be given only after verification that an onsite urine dipstick test for opioids, done immediately before the injection, is negative.

C. The injection should be administered as an intramuscular (IM) gluteal injection, alternating buttocks for each subsequent injection, using carton provided components only.

D. LAIN MUST NOT BE ADMINISTERED INTRAVENOUSLY OR SUBCUTANEOUSLY

E. LAIN must be kept refrigerated (36-46 degrees F) and not frozen. It should not be exposed to temperatures over 77 degrees F.

F. LAIN should not be stored at home by clients, or in any other off-site location.

VII. Provision of other services

A. LAIN is adjunctive to other treatment for SUD.

B. Clients who are receiving LAIN therapy should participate in the same manner as other clients in all other clinic services, including both psychotherapy and medication services, and should not be restricted to special LAIN groups.

VIII. Treatment Monitoring and Duration

A. LAIN treatment should continue only when ongoing monitoring and associated documentation supports the determination that client is tolerating and responding to LAIN and there continues to be a medical need for further use.

B. LAIN treatment should continue only as part of an ongoing comprehensive treatment program for opioid or alcohol use dependence that should include psychosocial support.

C. Patient must not be receiving opioid analgesics.

D. Treatment beyond six months requires review and approval by the responsible supervising psychiatrist, as safety and tolerability of long-term treatment has not been established.

IX. Special precautions: DMH outpatient staff providing LAIN treatment should be familiar with all LAIN warnings and contraindications. Critical warnings and contraindications include:

A. **Hepatotoxicity:** Naltrexone can cause hepatotoxicity when given in excessive dosages. It is contraindicated in clients in acute hepatitis and liver failure, and its use in clients with active liver disease must be carefully considered in light of its hepatotoxic effects.

B. **Injection Site Reactions:** Naltrexone injections may be followed by pain, tenderness, induration, swelling, local erythema, bruising, or pruritus. Severe reactions such as prolonged induration, hematoma, cellulitis, abscess, sterile abscess, and necrosis may require a surgical consult and intervention.

C. **Eosinophilic Pneumonia:** Eosinophilic pneumonia requires hospitalization and treatment with steroids and antibiotics.

D. **Hypersensitivity Reactions Including Anaphylaxis:** Cases of urticarial, angioedema, and anaphylaxis have occurred with LAIN injections. Clients should seek immediate medical attention and should not continue with LAIN therapy.

E. **Unintended Precipitation of Opioid Withdrawal:** This can occur when providers are unaware of client opioid use or in instances where a naloxone challenge test was not performed.

F. **Opioid Overdose:** Opioid overdoses can occur when clients attempt to use opioids during treatment and immediately after being on LAIN following an injection period.

G. **Depression and Suicidality:** Alcohol and opioid dependent clients should be screened and monitored for the development of depression or suicidal thinking and, if present, should be assessed and treated.

H. **Reversal of LAIN Blockade for Pain Management:** In emergency situations when LAIN treated clients develop pain, regional analgesia or use of non-narcotic analgesics is recommended. If opioid medication is required, the client should be managed in a hospital setting or a setting that can provide cardiopulmonary resuscitation services.

Attachment 2 **Urge to Use Scale***

* The Urge to Drink Scale is a modified version of the PACS. The rationale and psychometric properties of the PACS can be found in:
Flannery BA, Volpicelli JR, Pettinati HM. Psychometrics Properties of the Penn Alcohol Craving Scale.

Name: _____ **Date:** _____

INSTRUCTIONS: The following questions are designed to help you assess an important aspect of your recovery status: the urge to use. Complete the form by thinking about the <u>past week</u> and placing a check mark next to the response that is most true for you.

1. How often have you thought about using would make you feel during this period?

- o Never, that is, 0 times during this period of time. (0)
- o Rarely, that is, 1 to 2 times during this period of time. (1)
- o Occasionally, that is, 3 to 4 times during this period of time. (2)
- o Sometimes, that is, 5 to 10 times during this period or 1 to 2 times a day. (3)
- o Often, that is, 11 to 20 times during this period or 2 to 3 times a day. (4)
- o Most of the time, that is, 20 to 40 times during this period or 3 to 6 times a day. (5)
- o Nearly all of the time, that is, more than 40 times during this period or more than 6 times a day. (6)

2. At its most severe point, how strong was your urge to use during this period?

- o None at all. (C)
- o Slight, that is a very mild urge. (1)
- o Mild urge. (2)
- o Moderate urge. (3)
- o Strong urge, but easily controlled. (4)
- o Strong urge and difficult to control. (5)
- o Strong urge and would have used if it were available. (6)

3. How much time have you spent thinking about using or about how good using would make you feel during this period?

- o None at all. (0)
- o Less than 20 minutes. (1)
- o 21-45 minutes. (2)
- o 46-90 minutes. (3)
- o 90 minutes — 3 hours. (4)
- o Between 3 to 6 hours. (5)
- o More than 6 hours. (6)

4. How difficult would it have been to resist taking a using during this period of time if you had known drugs were in your house?

- o Not difficult at all. (°)
- o Very mildly difficult. (1)
- o Mildly difficult. (2)
- o Moderately difficult. (3)
- o Very difficult. (4)
- o Extremely difficult. (5)
- o Would not be able to resist. (6)

5. Keeping in mind your responses to the previous questions, please rate your overall drug urge to use for the stated period of time?

- o Never thought about using and never had the urge to use. (0)
- o Rarely thought about using and rarely had the urge to use. (1)
- o Occasionally thought about using and occasionally had the urge to use. (2)
- o Sometimes thought about using and sometimes had the urge to use. (3)
- o Often thought about using and often had the urge to use. (4)
- o Thought about using most of the time and had the urge to use most of the time. (5)
- o Thought about using nearly all of the time and had the urge to use nearly all of the time. (6)